Sharing of Model Organism and Related Resources: Frequently Asked Questions (FAQs)

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Introduction

All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. The sharing of model organisms for research purposes is important, because reproducibility is a key tenet of science and it demonstrates proper stewardship of public funds. It is expected that establishment of such plans as a term of award will foster more rapid scientific progress by avoiding the use of limited resources and investigator time to reproduce previously developed model organisms.

Definitions, Policy, Applicability, and Rationale

Q1: For purposes of this policy, what organisms are considered "model organisms," and what are related research "resources" that must be added?

A1: The term "model organism" includes mammalian models, such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, roundworm, Arabidopsis, fruit fly, zebrafish, and frog. Examples of model organisms for which a sharing plan is expected when new, genetically modified organisms are developed is posted on the NIH Model Organism for Biomedical Research Web site (http://www.nih.gov/science/models/). This list is updated periodically. Although genetic variants of viruses, bacteria, and other prokaryotic organisms should be made widely available pursuant to the NIH policy (see FAQ4), at this time NIH is not expecting the submission of a sharing plan from investigators who intend to develop non-eukaryotic organisms. Genetically modified organisms are those in which mutations have been induced by chemicals, irradiation, transposons or transgenesis (e.g., knockouts and injection of DNA into blastocysts), those in which spontaneous mutations have occurred, and congenic or consomic strains. Depending on accepted practice, new, genetically modified model organisms developed with NIH funding may be shared as mature organisms, sperm, eggs, embryos, or even the vectors used to generate transgenic or knockout organisms (refer to FAQ 17). The term "resources" includes materials and data necessary for the production and understanding of model

organisms, such as vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Q2. Are materials from humans considered research resources, for the purposes of this policy?

A2. The Notice only applies to non-human model organisms. Other than established cell lines, human specimens would require informed consent. This policy does not apply to human cells that are not commercially available.

Q3: What is NIH policy regarding the distribution and sharing of mutant strains of model organisms created with NIH funds?

A3: The NIH expects that new, genetically modified model organisms and related resources generated with the aid of NIH funding will be distributed and shared with the scientific community in a timely way, generally at least upon publication of the primary results announcing the development of the genetically modified model organisms. Investigators submitting an NIH application (including competing renewals) are expected to include a concise plan addressing the timely distribution of organisms and resources, unless the proposed research will not generate new model organisms and related resources.

Q4: Is this a new policy?

A4: No. This statement describes implementation guidelines for existing NIH Grants Policy, [NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2003/index.htm) and Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999 (http://ott.od.nih.gov/NewPages/RTguide_final.html)].

Q5: For what types of awards does the sharing plan policy apply?

A5: This policy applies to extramural investigators who anticipate generating new, genetically modified model organisms and related resources pursuant to any type of NIH award—grants, cooperative agreements, and contracts, including SBIR and STTR awards. Guidelines already in place for the NIH intramural research program are consistent with those for the extramural community (for example, see http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/resources.htm).

Q6. The policy presumably applies to all R mechanisms, but does it also apply to P01s or other P mechanisms?

A6. Yes. In some cases, different subprojects will have different sharing plans, or only one or a few of the subprojects will need sharing plans. It will be important to make clear in the application whether the PI or the head of the subproject will be responsible for the implementation of the proposed sharing plan(s).

Q7. Does the policy apply to SBIRs and STTRs?

A7. Yes. SBIRs and STTRs are also expected to include a sharing plan if animal models are to be created, or state why sharing is restricted or not possible.

Q8.Does this policy apply to individual fellowships (F's)?

A8. Generally, no. The expectation is that any model organisms would be covered under their mentor's research.

Q9. Does this policy apply to institutional training grants (T's)?

A9. No.

Q10. Does this policy apply to individual Career Development awards (K's)?

A10. Yes, if the scope and aims of the project include the development of model organisms.

Q11. How does the NIH model organism sharing policy differ from the NIH data sharing policy?

A11. The model organism sharing policy covers all projects that produce or may produce model organisms, regardless of the amount of the budget. Although data sharing plans are not routinely expected for projects requesting less than $500,000 in direct costs in any year, investigators who produce model organisms, including projects requesting less than $500,000 in direct costs in any year, are expected to provide a sharing plan for model organisms and related research resources.

Q12: Why should I make my model organisms and related resources available to the scientific community?

A12: The timely distribution of unique research resources furthers research and scientific progress without needless and costly duplication of effort. It also enables other investigators to extend the scope of research to investigation beyond that envisioned by the creator of the animal strain. Resources afford rich opportunities for new areas of inquiry, because there is inevitably more that could be learned about them than a single investigator could envision or pursue. By making resources more widely available, students, postdocs, and investigators have the

opportunity to expand the scope of their research and generate new training opportunities. Thus, everyone benefits, including investigators, the scientific community, and the public, from broader access and use of these important scientific resources. Expanded training and the availability of model organisms and related resources for the scientific community may lead to more rapid breakthroughs for diagnosis, prevention, and treatment of disease and for improvements in public health. These goals are central to the mission of the NIH.

As the creator of a shared resource, your reputation is enhanced when your model organisms are used in other laboratories' studies and subsequently cited in publications. Finally, sharing your resources is good insurance, should there ever be a disaster in your laboratory resulting in the destruction of your strains. In recent history, disasters such as floods at Baylor University, fires at The Jackson Laboratory, and power outages at Columbia University have occurred that have resulted in loss of valuable mouse strains and other resources.

Q13: Is sharing and distribution of unique resources such as model organisms and related resources with the scientific community widely accepted as good practice?

A13. Yes. Journals such as *Proceedings of the National Academy of Sciences USA*, *Cell*, *Nature, Neuron*, *Immunity*, *The Journal of Immunology*, *The Journal of Neuroscience*, and *Science* require investigators to make unique resources available so that the results can be verified and additional research promoted. Both the Society for Neuroscience, with a membership of 29,000 scientists, and the Federation of American Societies for Experimental Biology (FASEB), consisting of 19 societies and a membership of 66,000 scientists, have taken positions that are consistent with the NIH policy. The policy of the Society of Neuroscience is that "unique and propagatable [sic] research materials used in studies being reported must be made available to qualified scientists for bona fide research purposes"(see http://apu.sfn.org/content/AboutSfN1/Guidlines/guidelines.htm and http://apu.sfn.org/content/AboutSfN1/Guidlines/guidelines.pdf) under section 1.8 of "Guidelines: Responsible Conduct Regarding Scientific Communication," Society for Neuroscience, 1998). In 1999, a letter from David G. Kaufman, MD, PhD, FASEB President, to Barbara McGarey of the NIH Office of Technology Transfer stated that the FASEB endorsed the policy for sharing unique resources described in the document "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts" (see http://www.faseb.org/opar/letters/1999/McGarvey.html).

Q14. Does this policy apply to international collaborations and foreign grants?

A14. Yes. If the U.S. institution is the primary grantee, then the domestic institution is responsible for its subgrantee or subcontract arrangements and is expected to ensure that this policy is adequately addressed in the application.

Q15. How can NIH help?

A15. NIH can help, for example, by encouraging use of existing repositories, encouraging applicants to request funds in their applications for expenses associated with sharing model organisms and data, providing administrative supplements for unanticipated expenses associated with sharing, and fostering outside of NIH a community standard of sharing, for example, through coordination with professional societies and with journals.

Considerations for Developers/Providers of Model Organisms

Q16: My colleagues and I spent considerable time, energy, and resources generating and characterizing the resources we created. We want to maximize the fruits of our labor. Can we delay sharing until at least publication so other experiments can be performed and manuscripts prepared?

A16: Yes. NIH recognizes that the investigators who generated the resources have a legitimate interest in benefiting from their investment of time and effort. However, deliberately delaying publication to prolong exclusive use of the reagents, strains, protocols, or cells is not in the best interests of the research community or the public health. Therefore, not sharing resources for a prolonged period will generally not be considered an acceptable plan. Furthermore, it may not be in your best interest as an investigator, as other researchers may end up with the credit for generating comparable resources.

Q17: If I made a knockout or transgenic animal, can I distribute only the DNA vectors?

A17: Generally, providing the vector only is inadequate, because it is time-consuming and expensive to recreate the genetically modified model organism, and it may not be possible to reproduce the exact allele. In some unusual cases, providing the vectors used in the generation of transgenic or knockout animals, rather than the animals themselves, may be an efficient way to share resources. A sharing plan that proposes to provide the vectors, rather than the model organisms, should justify that plan based on cost or feasibility or other relevant factors, and specifically address whether the recipient can generate an identical allele.

Q18: Can I patent my model organisms and related resources to protect the property rights of my institution, such as intellectual property rights?

A18: Yes. You and your institution may choose to retain title to subject inventions such as a mutant mouse developed with federal funding, under the provision of the Bayh-Dole Act. However, a patented resource must still be made reasonably available and accessible to the research community in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2003/index.htm), including the NIH Research Tools Policy (http://ott.od.nih.gov/NewPages/RTguide_final.html).

Q19: Could patenting interfere with the distribution of mutant animals to the scientific community?

A19: Patenting of mutant strains could possibly interfere with distribution to the scientific community if such patents are enforced inappropriately. However, the NIH Research Tools Policy provides guidance on the appropriate implementation and use of intellectual property. This policy also provides for reasonable availability and accessibility of such resources to effectively further the research enterprise (http://ott.od.nih.gov/NewPages/RTguide_final.html).

Q20: What types of material transfer agreements (MTAs) are acceptable under NIH policy?

A20: NIH does not require the use of a particular MTA for transfers of materials developed with NIH funding. However, when an institution uses an MTA to make a transfer to a not-for-profit entity, the terms generally should be no more restrictive than those in the Uniform Biological Materials Transfer Agreement (http://ott.od.nih.gov/newpages/UBMTA.pdf). For transfers of organisms, institutions may wish to consider the recently developed Material Transfer Agreement for the Transfer of Organisms (MTA-TO) used by the NIH, which contains terms specific to the transfer of animals (see http://ott.od.nih.gov). For transfers of related research resources, institutions may wish to use the Simple Letter Agreement (SLA) provided at http://ott.od.nih.gov/NewPages/SimplLtrAgr.pdf, or another document with no more restrictive terms, to readily transfer unpatented tools developed with NIH funds to other recipients for use in NIH-funded projects. If the materials are patented, other arrangements such as nonexclusive or exclusive patent licensing may be used, and the materials may be sold to the research community in a manner that promotes their widespread distribution. However, material transfer agreements containing commercialization option rights, royalty reach-through, or product reach-through rights back to the provider are inappropriate. Similarly, when for-profit entities seek access to NIH-funded tools for internal use, recipients should ensure that the tools are transferred with the fewest encumbrances possible. The SLA may be expanded for use in transferring tools to for-profit entities, or simple internal use license agreements with execution or annual use fees may be appropriate. [http://ott.od.nih.gov/NewPages/RTguide_final.html] There may be additional issues regarding animal resources. Therefore, you should confer with your organization's technology transfer office and sponsored research program office to transfer novel animal strains. Your transfer agreement may also need to address issues of animal custody, care, and use under all applicable Federal laws, including but not limited to the Animal Welfare Act. Therefore, you also may wish to confer with your institution's office responsible for animal welfare.

Q21: If I receive funding from both the NIH and a biotechnology company and the company's sharing policy conflicts with the NIH, which policy should I follow?

A21: Organizations receiving funding from the NIH must have policies and procedures in place to ensure that any agreements entered into with third parties are consistent with the terms and conditions of their NIH funding award, including the provision of intellectual property rights to the NIH, and that third parties are informed of the NIH requirements [see the NIH Grants Policy

Statement for guidance (http://grants.nih.gov/grants/policy/policy.htm)]. Therefore, to remain in compliance with the NIH award, you will need to revise any third-party agreements that are inconsistent with the terms and conditions of an NIH award. For guidance, see "Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts" (http://grants.nih.gov/grants/guide/notice-files/NOT94-327.html) and "Intellectual Property Reporting for NIH Grantees That Also Have Involvement with the Veterans Administration" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-033.html). You must seek appropriate approval from the NIH should you wish to waive or assign title to another party. Finally, you must ensure that rights to inventions arising out of NIH funding agreements are properly assigned to the institution in order to fulfill your responsibilities under the funding agreement.

Q22: It may be costly to share model organisms and related resources. How can I defray these expenses? Can I charge money to investigators requesting model organisms and related resources?

A22: Investigators may request funding from NIH to defray reasonable costs associated with the sharing of model organisms and related research resources. Such funding may cover the costs of sharing under the investigator's auspices, or costs associated with the transfer of model organisms and resources to repositories whose goal is to distribute organisms broadly to the research community. Recipients of NIH funding also can recover the costs associated with sharing including shipping expenses as a reasonable charge to the recipient. However, charges in excess of associated costs incurred on the NIH grant(s) need to be reported as program income. (See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). Managing program income is complex and would require involvement of your office of sponsored programs or technology transfer office.

Q23. I am a scientist at a small business research company that develops mutant mouse models for use within the company as drug screening tools. The distinguishing competitive advantage that my company has is based upon these mice. If I receive NIH funding, will I be forced to distribute the mouse mutants?

A23. Companies receiving NIH funding, including SBIR or STTR awards, are expected to include a sharing plan if new, genetically modified model organisms and related resources are to be created, or state why such sharing is restricted or not possible. Because reproducibility is a key tenet of science, the sharing of model organisms for research purposes is extremely important to the NIH. There must be compelling reasons why sharing must be restricted or is not possible.

Q24: I am an investigator affiliated with a small business that produces mutant mouse models and sells them. Distributing my organisms for only the cost of shipping and handling is not compatible with our business plan. If I receive NIH funding to produce a mouse model, can I sell it for profit beyond the costs of shipping and distributing? What are my options?

A24: NIH policy encourages the wide availability of resources developed with NIH funding. Organisms and resources may be made widely available through nonexclusive or exclusive patent licensing, and your company or another distributor may sell the invention to the research community in a manner that promotes widespread distribution and reasonable accessibility. Any program income must be reported to NIH (See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

Q25: I don't want to share my novel animal strains or the reagents used to make them. Can I be forced to do so?

A25: Sharing of research resources is a very important NIH policy and is included as a term and condition of your award. NIH expects that you include a plan for sharing new model organisms and related resources in your application. Failure to provide an adequate sharing plan may affect the Institute's decision to make an award. If there are legitimate reasons for not sharing, these should be presented for consideration. The Scientific Review Group may comment on your sharing plan during the peer review of your application. If your application is selected for an award, NIH program staff (in consultation with other NIH staff as appropriate) will review and ask you to address and resolve any concerns about the sharing plan (as well as any other issues raised in the review). These issues must be resolved before an award is made. If your application is funded, you will be expected to share according to the sharing plan consistent with NIH policy. Failure to comply with your sharing plan may be carefully considered in future funding decisions for you and your institution.

Q26: What are the different means of sharing strains of model organisms?

A26: There are many ways to share strains of model organisms. For example, you can share under your own auspices, or you can deposit the resource in a repository or stock center. If an appropriate repository exists, you are encouraged to donate the resource to a repository, preferably one funded by the NIH. Examples of available resources are posted on the NIH Model Organism for Biomedical Research Web site (http://www.nih.gov/science/models/), and are updated periodically.

Q27: The expectation that I provide thousands of live animals to the scientific community puts an unnecessary burden on my laboratory. Breeding and maintaining animals, especially mammals, is much more laborious and costly than constructing and maintaining a plasmid. If I need to provide animals to other investigators, I will have to hire a technician and request more space in the mouse colony or animal housing facility. Even if I do this, I may not be able to respond to investigators' requests, because the number of animals that I can breed is barely adequate for my own research program. How do I deal with this problem?

A27: A solution to this problem may be to provide the strain to a commercial vendor or to a national repository that distributes model organism strains consistent with NIH policies. Stock centers or repositories ensure that the unique strains are appropriately archived and distributed

under strict standards of genetic quality and animal health. These repositories can propagate the animals and, for example, in the case of mice and zebrafish, cryopreserve sperm and/or embryos. This provides you with a way to share your animals consistently without unduly burdening your laboratory and your institutional animal facility. Your breeding efforts could then be focused on your own laboratory's needs and those of your collaborators, or your own laboratory and your collaborators could also utilize the repositories for obtaining model organisms consistently.

Q28: Suppose all of the available repositories refuse to accept my strain. What should I do then?

A28: Repositories, stock centers, and vendors may refuse to carry mutant strains for a variety of reasons. They may believe that the stock will be too difficult to maintain or that there may not be sufficient demand for it. It is also possible that a repository is already at capacity or is refusing to accept new stocks because it is having a problem with disease. Finally, many repositories refuse to accept mutant stocks if they are not well characterized or if there are too many of the stocks to accommodate. If you cannot find a repository that will accept your stocks, you will have to pay for the cost of distributing model organism strains. If you do not have funds for this in your grant budget (see below), you should ask your program officer about available avenues for supplemental funding (e.g., administrative supplements, competitive supplements) and associated requirements. See also FAQ 22.

Q29: Because I anticipate relatively few requests, I'm planning to share under my own auspices. Nevertheless, this will cost technician time and may require supplies or equipment for shipping. How am I supposed to cover these expenses?

A29: You should request funds from NIH to pay for costs associated with stock maintenance and distribution in your application. If the requirement arises after the grant is awarded, you can submit a request for an administrative supplement for these funds. You should make it clear in the budget justification, the research plan, and the animal subject section what your sharing plan is and what costs are associated with implementation of it. See also FAQ 22.

Q30: I don't anticipate a very big demand for my mutants, but I don't have the time or resources to respond to requests. Are there alternatives to sharing under my own auspices or depositing stocks in a repository?

A30: Worms, fungi, and most prokaryotes can be frozen or freeze-dried. When submitting mice strains to some repositories (such as the Mouse Mutant Regional Resource Centers, see http://www.mmrrc.org), it is possible to request that they be stored as cryopreserved embryos rather than as live stocks. Frozen sperm can be stored at zebrafish stock centers.

Q31: When I share a novel strain, am I also supposed to share associated records and protocols?

A31: Yes. You are expected to share any appropriate PCR assay protocols, primers, tissues, DNA, or other reagents or information necessary for PCR assays and genotyping of the strain. Distribution of other research tools related to the strain should also be addressed in the sharing plan. It is acceptable to state that some of the information about the strain will be disclosed in your publications.

Q32. Is depositing of phenotype data expected?

A32. Yes, published phenotype data *linked* to organisms is considered a related resource and should be shared as well unless there is a legitimate reason not to share.

Q33: Do I need to use standard genetic nomenclature?

A33: Yes. To facilitate communication and consistency, stock centers and repositories use standard strain nomenclature for the strains they maintain. After a strain has been deposited in a repository, the investigator who provided it should use the nomenclature designated by the repository in all subsequent publications on the strain, at least once in each publication, and note that the strain has been deposited in that repository.

For mice, investigators should obtain approved genetic nomenclature for each strain from the Mouse Genome Informatics (MGI) nomenclature committee (http://www.informatics.jax.org/mgihome/nomen/) before submitting the strain to a repository, or they must obtain approved nomenclature from the repository to which they submit the strain. MGI provides an online submission form as well as assistance with gene and strain nomenclature. Strain names should always include the Lab Code to show clearly the source of the mice used. Lab Codes can be obtained from the Institute for Laboratory Animal Research (ILAR), at the National Academy of Sciences. The ILAR Web site (http://dels.nas.edu/ilar/) provides an online submission form and a database of existing registered Lab Codes.

For other model organisms, investigators should consult the appropriate database (e.g., Rat Genome Database for rat, http://rgd.mcw.edu; the Zebrafish Information Network for zebrafish, http://zfin.org; Flybase for Drosophila, http://flybase.bio.indiana.edu; Wormbase for *C. elegans*, http://www.wormbase.org; etc.) to ensure that they are using proper nomenclature for the mutant, variant, or allele.

Q34: How well does the novel strain need to be characterized before it is deposited in a repository?

A34: Criteria for acceptance of model organism strains and resources vary among repositories and stock centers, and among species. Information on repositories' Web sites, or from phone conversations with repository personnel, may provide guidance. It is prudent to document communications in writing to ensure that there is no misunderstanding about requirements.

Q35: How can I make it clear to the scientific community that a novel strain is available?

A35: The best way to "advertise" the availability of novel strains is through peer-reviewed publications and presentations at national and international meetings. Additionally, if you deposit a strain in a stock center or repository, it will appear on the repository's list of available strains, which can be searched by other researchers.

Q36: What is my responsibility if the mutant strain that I made becomes infected with a pathogen at some point during its generation and breeding?

A36: It is advisable that research animals be maintained in a facility that has an adequate health monitoring program or that investigators state a basic list of pathogens that must be tested for in any facility. Animals known to be infected with pathogens or from a colony known to harbor pathogens should not be distributed unless the recipient is notified and has facilities to quarantine and/or rederive the animals, because disease status can alter the results of experiments. Should the investigator become aware that the research organisms became infected during their creation and generation, the investigator should take steps to eliminate the infection. Stock centers and national repositories have routine quarantine and acquisition policies that are designed to detect and eliminate infection.

Q37: How do I ship vertebrate animals either to a repository or to a requesting investigator?

A37: In either case, you should talk to a representative of your Laboratory Animal Care Unit at your institution and seek guidance. These units ship and receive animals on a regular basis and will provide you with the necessary help and information. If the vertebrates are regulated by USDA, the Animal Welfare Regulations should be consulted, because they provide exact requirements. Additionally, if you plan to submit your strain to a stock center or repository, you will need to contact the repository to make the appropriate shipping arrangements.

It is mandatory for providers and requestors to comply with all current Federal guidelines for shipping hazardous materials.

Q38: I am an investigator who receives NIH funding. What are the rules regarding shipping organisms?

A38: Regulations may vary from State to State within the United States. For information on importing animals into the United States, please contact the Veterinary Services office in the destination State. For information on exporting animals from the United States, please contact the Veterinary Services office in the origination State. A list of Veterinary Service offices can be found at the USDA Animal Regulations Library Web site (http://www.aphis.usda.gov/vs/area_offices.htm).

Under some circumstances, a USDA permit may be required. Please consult the USDA (http://www.aphis.usda.gov/vs/ncie/) for more information.

You should also check with the Centers for Disease Control and Prevention (CDC) for their current guidelines regarding importation of animals to the United States (http://www.cdc.gov/od/ohs/biosfty/imprtper.htm).

Exports and imports fall under the jurisdiction of the U.S. Department of Commerce. For additional information, call (202) 501-7900 or visit their Web site to obtain additional contact information (http://www.commerce.gov).

Your institution should be able to provide guidance regarding export, import, and shipment of organisms and related research resources. You should confer with offices at your institution for guidance.

Writing the Sharing Plan, Review, and Progress Reporting

Q39: Where should the sharing plan appear in my grant application?

A39: Scientists submitting a grant application are expected to include a sharing plan or to state why sharing is not possible. The plan should be described in a brief paragraph to be placed in the Research Plan section (i.e., immediately after PHS 398 Section F. Vertebrate Animals, Rev. May 2001) so it does not count toward the application page limit. Additional information on sharing might be included in other sections of the application, as appropriate. For example, if you are producing an important resource for the scientific community, you probably want to mention this in the Significance section. For some grant applications, the Vertebrate Animals section may need special consideration regarding sharing. Institutional Animal Care and Use Committee and Animal Biosafety Level concerns could be addressed here without counting toward the application page limit (e.g., for Biosafety Level 3 agents in primates, etc.). If you are requesting funds to distribute animals or other resources, or to prepare, document, and archive associated data, you should make this clear in your budget and budget justification.

If there are extenuating circumstances that would prohibit compliance with the sharing plan policy, your application should include an appropriate justification for the inability to share.

Q40: What should be addressed in my sharing plan?

A40: Sharing plans may vary, depending on the organism, the nature of the resources that will be shared, the extent to which intellectual property issues may be considered in sharing, and your plans for distributing the resources. Your plan should specify:

- How you will make your novel strains available to the scientific community, including:
    - The form in which you will provide the organisms (e.g., adults, embryos, sperm);
    - Related research resources and data that you will provide;

  - A reasonable time frame for periodic deposition of material and associated data;
  - Whether you will share under your own auspices or use a repository, and, if a repository, which one; and
  - For vertebrate animals and for other species for which pathogens or contaminants are potentially serious problems, how you will maintain your strains to minimize the risks of infection or contamination.

- How you will handle technology transfer and intellectual property issues, including:
  - How the institution plans to make such organisms and resources widely available to the research community;
  - How the institution plans to make certain any rights or obligations to third parties are consistent with the terms and conditions of the NIH award to ensure appropriate dissemination of model organisms or reagents under the NIH award; and
  - A description of the mechanisms that will be used to distribute organisms and related research resources (e.g., materials transfer agreements).

Samples of model organisms sharing plans may also be found at http://www.nih.gov/science/models.

Q41. What if my project did not initially set out to make any model organisms and, after award, genetically modified animals are made?

A41. In such a case, it would still be appropriate to share such model organisms consistent with NIH policies, and it would be appropriate to consult with the NIH program official and include a sharing plan in the next noncompeting application or in a separate letter.

Q42: I do a large genetic screen and generate thousands of lines. Only a few of them have a phenotype that is of interest to my laboratory. Am I required to maintain and distribute all of the lines?

A42: In general, no. If you know nothing about the lines except that they do not have a specific phenotype, and your description of them in a publication is limited to the cross used to generate them and the number of lines screened, there would be no need for you to maintain or distribute those lines. If, however, you were funded to generate the collection of lines as a community resource, you would be obligated to share the lines.

Q43: Should I discuss my sharing plan with my institutional technology transfer office and business office?

A43: Yes. Issues surrounding the sharing plan and intellectual property can be highly complex. Plans should be developed in consultation with individuals from your institution who have expertise in this area, and consistent with NIH guidelines. Experts could be from your sponsored research office, your technology transfer office, your office of general counsel, and/or any other

appropriate office. The consultation will clarify the policies of your institution regarding sharing and distribution of research resources such as mutant mice, as well as your institution's policies regarding intellectual property and inconsistent obligations with third parties.

Q44: How will the adequacy of my sharing and distribution plan be evaluated?

A44: The Scientific Review Group, or study section, will comment on the adequacy of the sharing plan. Reviewers will be asked to describe their assessment of the sharing plan in an administrative note and, except in defined circumstances, will not include their assessment in the overall priority score. For some special initiatives, such as Request for Applications and Request for Proposals specifically directed to the development of model organisms, reviewers may be asked to integrate their evaluation of the plan for sharing with other review criteria and factor their assessment into the overall evaluation of scientific merit. Any concerns must be resolved before an award can be made. Program staff, who will review your sharing plan before making funding recommendations, should be your first point of contact for resolving sharing plan deficiencies.

Q45. What is expected of Scientific Review Administrators (SRA) and reviewers?

A45. Before the application is reviewed, the SRA should contact the investigator to obtain a sharing plan if one is required and there is none in the application. In most cases, it will be obvious to the SRA and to the reviewers whether a sharing plan is required. Whether a sharing plan is reasonable can be determined on a case-by-case basis, taking into consideration the organism, the timeline, the applicant's decision to distribute the resource or deposit it in a repository, and other relevant considerations.

Q46. Who reviews for budgetary concerns?

A46. Budget review would be part of the overall review consistent with usual NIH practice.

Q47. What does this policy mean for grants management?

A47. Grants management staff will ensure that an acceptable sharing plan is referenced in the Notice of Grant Award (NOGA) either by the standard reference to the funded application or by specific reference to a revised plan. The NOGA is a binding legal document. The terms and conditions incorporate, and the grantee accepts, the terms once funds are drawn to conduct the project. The Grants Management Officer works with NIH program staff to complete this process and address enforcement if the plan is not followed. Recognizing that circumstances can change, grants management and program staff will work with grantees to renegotiate sharing plans as necessary.

Q48: Will I have to document sharing of resources in my annual progress reports?

A48. Yes. You should report the number of requests received and number fulfilled when submitting your non-competing renewal progress report as well as your Final Progress Report.

Q49: Now that the model organisms exist, I find that my proposed plan in the original grant application no longer provides the most effective way to broadly disseminate them to the research community. What do I do in this case?

A49: As the expectations and tools available to facilitate model organism sharing continue to evolve, maximum flexibility is encouraged to allow for renegotiations during the project period at the request of either the Institute/Center or the funded institution in response to materially new and/or unforeseen information or developments. You should discuss your sharing plan with your NIH program contact who can work with you to modify your sharing plan accordingly.

Q50. If the aim of my NIH-funded project is to create a model organism, the grant likely will end shortly after its creation. What happens after the grant ends or the investigator leaves the institution?

A50. The sharing plan holds for the life of the grant. You should address how you and/or your institution plan to make your model organism available after the grant has expired, such as through cost-reimbursable charges or donation to a repository. Repository use is encouraged to provide for easy long-term access.

Q51. Will each Institute or Center make its own decisions about penalties if investigators do not comply with their sharing plans?

A51. Each Institute or Center will determine an appropriate response, consistent with the NIH guidelines, if the terms and conditions of award are violated.

Considerations for Requestors/Recipients of Model Organisms

Q52: How do I find out what strains are available from other investigators and repositories?

A52: You can obtain this information from publications and electronic databases. Also, Web sites of stock centers and repositories list the available stocks and strains.

Q53: If I acquire a resource and sign a Material Transfer Agreement (MTA) not to distribute it, am I obligated to share it?

A53: You are not expected to share the resource that you acquired from another source. However, if you use that resource to breed, construct, or generate another resource using NIH funds, you would be obligated to share the derived resource. For example, if you use a Drosophila stock that you cannot distribute to generate new mutant lines using NIH funds, you would be obligated to share the new lines.

The MTA or Simple Letter Agreement (SLA) would state whether you can distribute the improved organism. If you do not have an MTA or SLA in obtaining the material, then there may be no applicable restrictions. It is best to confer with your institution's technology transfer office for guidance.

Q54: What can I do if I believe an investigator is refusing my request for strains or other resources?

A54: Submit a request to that investigator in writing, even if you suspect that it will be denied. Include a brief outline of your research objectives and, where relevant, Institutional Animal Care and Use Committee (or equivalent) approval information. If the response letter provides a reasonable explanation for why the resource is not currently available, you should try to find another source. On the other hand, if the investigator does not respond to your request, or if you are not convinced that the investigator's explanation for why the resource cannot be shared is valid, you should first confer with your own organization's technology transfer office and/or office of sponsored programs for guidance. You should also discuss the situation with your NIH program officer.

Q55. I am an investigator without NIH funding. What should I do if I encounter an investigator who refuses to share NIH-funded model organisms or related resources? I do not have a program officer to contact.

A55. Send a written request to the investigator specifying the objectives of your research and, if relevant, your Institutional Animal Care and Use Committee (or equivalent) approval information. If you do not receive a response or you think that the response is inadequate, you should confer with your own technology transfer office and/or office of sponsored programs for additional guidance. You may also consider contacting the NIH Institute/Center that supported the grant under which the model organism was produced. If you cannot identify the NIH Institute/Center, you may consider contacting staff in the NIH Office of Extramural Research or the Extramural Technology Transfer Policy Staff at the NIH Office of Technology Transfer.

Q56: I am an investigator without a biosafety level 3 containment facility, requesting a strain to be used in an experiment studying an infectious agent that requires a BSL-3 facility. Can the creator of the strain refuse to provide it?

A56: The provider of model research organisms should not release them into a situation without confirmation that they will be properly contained and maintained. The transfer agreement

document(s) should address issues of animal custody, care, and use under all applicable Federal laws, including, but not limited to, the Animal Welfare Act. One useful reference is the NIH/ARAC Animal Transfer Agreement, which is available at http://oacu.od.nih.gov/ARAC/transfer.htm. Your technology transfer office, office of sponsored research programs, and/or office of animal care should be consulted, as appropriate, for such transfers.

Q57: If an investigator without Institutional Animal Care and Use Committee (or equivalent) approval requests a strain of a vertebrate animal from the creator of the strain, can the provider deny the request?

A57: The requestor's institution is responsible for ensuring that all requirements for animal care and housing are satisfied. For the provider, some simple answers regarding animal care and, for example, in the case of mice or rats, the availability of a veterinarian responsible for such animals at the requestor's institution, will clarify most issues. For guidance in formulating your information acquisition, consult the NIH/ARAC Guidelines, available at http://oacu.od.nih.gov/ARAC. For mice, another helpful reference is the Jackson Laboratory's Mice Orders New Customer Application Form (http://jaxmice.jax.org/orders/contact_information.shtml).

Q58: As a user of a shared model organism resource, what are my responsibilities for identifying in publications or presentations the strains that I use in my research?

A58: Users of the shared resource should acknowledge the source (repository or investigator), and reference the original citation describing the strains in their publications. They should use standard genetic nomenclature to designate the strains.

Q59: What is the proper way to identify the provider of resources in a publication?

A59: Scientific custom is to name providers of materials as authors if providers collaborate with recipients of organisms and contribute intellectually to the manuscript. Otherwise, it is appropriate for providers to be acknowledged as the source of research resources upon which the manuscript is based. Acknowledging the source of the resource upon which the manuscript is based follows best practices for scientific publication. This acknowledgement also helps identify the specific material used by identifying the source and should most appropriately go into the Materials and Methods section of the publication. See FAQ 33 about nomenclature.